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LABELS ON FOOD PRODUCTS -- THE PROTECTION THEY GIVE

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Industrialization of our society brought about a demand for foods processed outside the home. In many cases, this processing was done under most unsanitary conditions. As population increased and industrialization progressed, the lack of sanitary standards became a real menace to public health. A need arose for some controlling legislation.

Today the consumer's problem is much more complex than it was when foods were first processed outside the home. The consumer not only wants to be sure that the food he purchases is wholesome but also whether its composition has been altered in any way. Laws have been passed and amended many times. The responsibility for enforcing the law has been carefully set forth.

Numerous regulatory agencies in the Department of Agriculture and the Food and Drug Administration (DHEW), and State and local groups place a properly labeled, safe, varied, and abundant food supply on the retail market. Over the years, the consumer, who makes his choices from these food products, has learned to take this protection for granted.

It is necessary today to wage a continual battle against those who would undermine the confidence of our people in the protection afforded them these many years. Communication has advanced to the point where virtually everyone knows some facts about food composition and food technology. *The consumer knows much more than he understands.* In his desire to provide food for himself and his family that contains all the nutrients needed for health and longevity, he spends billions of dollars yearly for food supplements when, by and large, he could meet his needs with foods available in any reliable food market.

The correspondence we receive and the questions asked of us indicate that the consumer wants protection against fraud as he makes his choices in the market place. He wants to know what he gets for his money, but he seldom realizes that he may not get what he pays for unless he assumes some responsibility. The protection he seeks is provided by the Food and Drug Administration.

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Our readers, who work with the ultimate consumer, want to know what the law includes and how it operates so they can help the consumer (1) learn his responsibilities, and (2) take advantage of the protection provided by assuming these responsibilities.

In this issue of NPN we describe—

- The development of authorization for the Food and Drug Administration.
- Examples of how the people are protected.
- How the Food and Drug Administration authorization fits into a larger consumer-protection program.
- What nutritionists and others can do to help.

DEVELOPMENT OF A CONSUMER-ORIENTED LAW

Pure food and drug legislation began in the United States in 1848 with a law prohibiting the importation of adulterated or deteriorated drugs. This was followed by the "Tea Act" of 1883, and its amendment in 1897, the latter directed against several foreign products.

Public interest and opinion needed arousing to pass legislation for the control of domestic products, however. Harvey W. Wiley, Chief Chemist for the United States Department of Agriculture, was the crusader largely responsible for accomplishing this task. He appealed to women's organizations, who, in turn, spurred the necessary public sentiment to influence Congress.

The period in the United States from about 1900 to 1915 is often referred to as the "muckraking era." During this period the writings of Mark Sullivan, Walter Lippman, Samuel Hopkins Adams, Upton Sinclair, and others

exposed scandalous conditions in the stockyards and food processing plants that indicated the need for legislation to control labeling of food, drugs, and nostrums.

By 1905, public interest and opinion were so strong that Theodore Roosevelt, in a message to Congress, advocated a Federal food and drug law. The law was passed in 1906, and was strengthened by the Shirley Amendment in 1912. Subsequently, it was amended several times to cover specific products or situations. In 1935, Senator Copeland introduced an amendment to cover cosmetics. The present Food, Drug, and Cosmetic Act was passed in 1938. It has been amended several times to cover new developments, such as antibiotics, chemical additives, and pesticide residues on foods, and to define classes of drugs that require medical supervision for safe use.

It has been said that when President Theodore Roosevelt signed the Food and Drug Act and the Meat Inspection Act (USDA) on June 30, 1906, he put his signature to the most significant peacetime legislation in the history of the country. These laws established the responsibility of the Federal Government (and State governments) to protect the consumer by barring foods that are hazardous, adulterated, or misbranded.

Hazardous Foods

Before the Food and Drug Law was passed, a variety of chemical preservatives and coal tar dyes that could be hazardous to health were being used indiscriminately in foods. The passage of the law prohibited this practice.

Since that time levels of safety for all additives must be established before they may be used in foods offered for sale through channels of interstate commerce.

To further protect the consumer from hazardous foods, the law provides authority to monitor processing methods in canneries.

Adulterated Foods

At one time, the reported sales of "Vermont maple sirup" exceeded the production capacity of that State by about 10 times. Another example of adulterated foods was butter that contained other fats, such as lard. These products were not harmful, but they were not what the consumer believed he was purchasing. Today, all foods entering interstate commerce must have labels carefully informing the purchaser of the contents. It is, of course, the responsibility of the consumer to read labels.

Misbranded Foods

The Federal Food, Drug, and Cosmetic Act is essentially a labeling law. It is meant to inform the purchaser of the

contents of a package and to give certain information about the company with whom the purchaser is dealing. It also protects manufacturers, packers, and distributors of high-quality goods from unfair competition.

The label must not be false or misleading. It must be easily read and understood. Imitations must be prominently labeled. If the food is made of two or more ingredients, they must be listed by their common or usual names and in the order of their predominance in the food. The net contents must be stated in common units of weight or measure. The container must not mislead either. Even though properly labeled, the product must fill the package at the processing plant. This presents difficulties currently with products such as cereals and crackers that shake down with handling. Labels must also include the name and business address of the manufacturer, packer, or distributor.

For some foods, standards of identity and quality have been set. These are fixed by order of the Secretary of Health, Education, and Welfare.

A *standard of identity* indicates the ingredients of which a food is made and sometimes specifies the proportions. The standards require that certain basic ingredients must be used and designates others that may be used at the packer's option. No other ingredients may be added—even if specified on the label.

The addition of specified amounts of certain vitamins and minerals to staple products contributes to the nutritional health of the people. Enriched bread and flour, vitamin D evaporated milk, and vitamin A margarine are some of the products for which standards of identity have been established. Such products need not have the *required ingredients* listed on the label.

Standards of *quality* set a minimum below which foods must not fall unless appropriately labeled. This labeling must be in bold letters of a size specified according to the size of the can. Labels may read, "Below Standard in Quality, Good Food—Not High Grade." The reason for failure of food to meet the standard may also be given, such as "Not Well-Peeled, Unevenly Trimmed" or "Excessive Discolored Peas."

Labels containing claims made for foods or food supplements that cannot be substantiated also constitute misbranding. Foods or supplements that are properly labeled, but are promoted with false or misleading advertising or with books and other printed materials that give false information, may be considered misbranded if the promotional material is displayed with the product.

Any violation of these regulations or standards constitutes misbranding and is subject to prosecution by the Food and Drug Administration if products enter channels of interstate commerce. By far the largest number of violations fall in the area of misbranding.

FDA MOVES AGAINST VIOLATORS

Authority to enforce this Federal law has been vested in the Food and Drug Administration. On first offense, manufacturers, packers, and distributors of integrity who unknowingly violate the law are given the opportunity to destroy the food if it is contaminated or prepared under unsanitary conditions; or if improperly labeled, to withdraw the product until labeling is corrected.

Not all violations are inadvertent, however. For example, the production and sale of food supplements carrying extravagant health and beauty claims is such a lucrative business that fines incurred become a nominal production expense. When a product is barred from sale, it can be given a new name and new promotional material can be developed with only a short interruption in sales.

Such producers make the enforcement of the Federal Food, Drug, and Cosmetic Act difficult because they are willing to exploit their fellowmen for financial gain. The fact remains, however, that misbranding must be stopped wherever it occurs. Descriptions of typical Food and Drug Administration actions against violators follow.

Nutri-Bio

The Nutri-Bio Corporation manufactured a food supplement, made numerous claims that it promoted mental and physical health, and offered it for sale on an interstate basis.

This item was sold "door-to-door," often by individuals who purchased the product for resale and were not fully aware that they were selling a misbranded and highly questionable product. The obvious sincerity of the salesmen was a distinct asset in promoting sales.

In many localities these salesmen were apprehended and charged with selling misbranded merchandise.

In Buffalo, N. Y., for example, the product was seized and charges read as follows:

"Misbranded by false claims in accompanying promotional literature that products would cause the user to be alert, pleasant, calm, vibrant, feel well, and have a zest for living. They also bore false claims for promoting mental and physical health, happiness, sociability, enthusiasm, liveliness, vigor, awareness; and that they were of significant value for special dietary supplementation and therapeutic use because of ingredients of unsaturated fatty acids, inositol, para-aminobenzoic acid, rutin, biotin, bioflavonoid complex, hesperidin complex, choline, alfalfa, potassium, sulphur, copper, zinc manganese, magnesium and montmorillonite; and that everyone needs a food supplement. The products were further misbranded in that the labeling failed to bear adequate directions for use in treating and preventing hemorrhage of the eyes, diabetes,

high blood pressure, arthritis and bursitis, for which they were offered in a sales talk at a private home."

The seized products were destroyed.

Almost simultaneously, a seizure was made in Seattle. Charges in this instance read:

"Misbranded by false and misleading claims in promotional material including salesmen's kit, leaflets, and carton and bottle labels, and by oral claims of the salesmen that the products were effective for treating and preventing loss of appetite, constipation, hemorrhage of mucous membranes, palpitation of the heart, nervousness, dental caries, anemia, colds, flu, arthritis, heart disease; for rebuilding tissues broken down by cancer, and for preventing cancer's spread."

Again the products were destroyed.

Nutri-Bio was seized and destroyed partly because of accompanying literature that became labeling when offered with the product, and partly because false claims made by the dealer in sales talk could be interpreted as labeling. These examples illustrate why the Federal Food, Drug, and Cosmetic Act is essentially a labeling law.

"Calories Don't Count"

Books and advertisements including false and misleading claims for a product can, in effect, become labeling if displayed with the product. A good example of a book becoming labeling is, "Calories Don't Count", by Herman Taller, M.D. This book, written by a physician certified as competent to specialize in obstetrics and gynecology, was used to promote the sale of safflower oil products.

Although there is no evidence that Dr. Taller made any special study or published research in nutrition (animal or human), his book implies that safflower oil and safflower oil products are effective for weight control without regard to total caloric intake.

The claim is made that calories do not matter, yet the type of menu suggested is low in calories and thus is sure to effect reduction for most obese persons. The elimination of sweets, starches, ice cream, cream, all bread except gluten bread, fruit juices, fruits and vegetables above the familiar 5 percent class (percentage carbohydrate contributed), and alcoholic drinks demonstrates in reality that calories do count.

Seizures were made of copies of the book and (1) safflower oil capsules in New York City; (2) safflower seed oil, safflower mayonnaise, and safflower oil capsules in Richmond, Va.; and (3) safflower oil capsules with Vitamin B-6 in Pennsylvania.

In each case, placards and other promotional material indicated relationship between claims made in the book and the product offered for sale. Thus the book became labeling for the product.

In the case of safflower oil-reducing capsules seized in Glen Cove, N. Y., charges read:

"Misbranded by false claims in accompanying book entitled, *Calories Don't Count*, by Dr. Herman Taller, and package inserts that the article was effective to control body weight, to reduce and maintain slimness even while consuming many thousands of calories daily, to lower and control the cholesterol level of the blood, for the treatment of arteriosclerosis and heartburn, to improve the complexion, to increase resistance to colds and sinus trouble, to promote health, and to increase sexual drive."

The capsules and package inserts were destroyed. The book, "*Calories Don't Count*", was not destroyed. The law authorizes the Food and Drug Administration to bar from channels of trade, *foods* along with specific promotional material that are hazardous, adulterated, or misbranded. FDA authorization does not extend to books.

FDA AUTHORITY: PART OF A LARGER PROTECTION PATTERN

The FDA is part of a pattern far greater in scope than most persons realize. Together, the FDA, the USDA, and State and local regulatory agencies provide a veritable army to keep unwholesome and improperly labeled foods off the market.

Agencies other than FDA that are usually associated with protection against fraud include the **Post Office Department**, which has the authority to protect the consumer against those who would use the mails to defraud him. Protection against misleading advertising is provided by the **Federal Trade Commission**. Both of these agencies have the authority to prosecute violators. The **Better Business Bureau**, although not an enforcement agency, is concerned with (1) informing the public about all types of claims and products, and (2) educating producers to observe the spirit as well as the letter of the law.

IN CONCLUSION

Limitations of the Act

The product must enter channels of interstate commerce. The Federal agencies cannot take steps to apprehend or prosecute a violator unless the product is distributed for sale across State lines. A small organization may violate the law and FDA agents may be aware of this, but if distribution is on an intrastate basis, all FDA can do is notify State authorities.

This limitation of authority is sometimes poorly understood, and the Food and Drug Administration is criticized

because some consumers believe that State authorities have to assume the responsibility of the Federal agency.

There is always a lag between technology and legislation. Although the law has been amended many times, legislation is necessarily somewhat behind needs. Technology makes many new products possible. If products meet the requirements of the law, they may go on the market. As research establishes new knowledge, it may become important to amend the law to give the consumer (1) essential information about a group of products, or (2) protection against indiscriminate use of certain categories of products. A good example of this was the legislation covering such new developments as antibiotics and residue of pesticide chemicals on raw food crops. Legislation comes, however, only after careful study and consideration of all factors as they relate to producer and consumer.

Apathetic Public Hinders Enforcement

The late President Kennedy stated that the consumer had the right (1) to choose, (2) to be informed, (3) to safety, and (4) to be heard.

The agencies charged with the protection of consumer rights can (1) provide the information that will help the user make good choices, (2) bar hazardous foods from channels of trade, and (3) invite the consumer to voice his views—at public hearings and via correspondence.

Also inherent in his right to choose is the consumer's right *not* to become informed, *not* to state his views to those who can take them under proper consideration, and to conspire with the violator by the illegal purchase of products. This is particularly true of prescription drugs.

The consumer who does not accept the protection of the law and its attendant responsibilities jeopardizes himself and his money; he also hinders enforcement of a law designed for his welfare.

How Nutrition Workers Can Help

Those working at the local level can make a significant contribution to consumer protection by continually including guidelines for wise food purchasing in their programs. These guidelines might well include (1) the encouragement of habits of label reading and food shopping at reliable markets, (2) a warning against fast talking "door-to-door" salesmen, and (3) the development of a questioning attitude toward any extravagant claims for food products. The consumer should also know that the specific information on labels is assurance that FDA is vigilant and acting within the authority vested in it.